

Please type a plus sign (+) inside this box → ☐

PTO/SB/08A (08-00)

Approved for use through 10/31/2002. OMB 0651-0031  
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 of 2

### Complete if Known

Application Number	09/654,227
Filing Date	August 31, 2000
First Named Inventor	Wolfgang HEIL et al.
Group Art Unit	1617
Examiner Name	M. Bahar
Attorney Docket Number	PLOVIN-1A

### U.S. PATENT DOCUMENTS

Examiner Initials *	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup> (if known)			
SH	A1	4,621,079		Lachnit-Fixson et al.	11-04-1986	
SH	A2	5,569,652	A1	Beier et al.	10-29-1996	

### FOREIGN PATENT DOCUMENTS

Examiner Initials *	Cite No. <sup>1</sup>	Foreign Patent Document			Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sub>a</sub>
		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)			
SH	B1	WO	97/11680	A2	Elliesen et al.	04-03-1997	
SH	B2	CA	2,188,907		Dittgen et al.	02-27-2001	

### OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
SH	C1	Prosecution History of Corresponding international Application No. PCT/IB00/01213 at EPO.	
	C2	Casper et al., "Estrogen and Interrupted Progestin: A New Concept for Menopausal Hormone Replacement Therapy," <i>American Journal of Obstet Gynecol</i> , Vol. 168, No. 4, pp. 1188-1196.	
	C3	Lignières, "Oral Micronized Progesterone," <i>Clinical Therapeutics</i> , Vol. 21, No. 1, 1999, pp. 41-60.*	
	C4	Nickisch et al., "Acid-Catalyzed Rearrangements of 15 $\beta$ ,16 $\beta$ -methylene-17 $\alpha$ -pregnene-21,17- $\alpha$ -carbolactone Derivatives," <i>Tetrahedron Letters</i> , Vol. 27, No. 45, 1986, pp. 5463-5466.	
	C5	Translation of Cite No. C4.	
	C6	Shah et al., "Preformulation Study of Etoposide: identification of Physicochemical Characteristics Responsible for the Low and Erratic Oral Bioavailability of Etoposide," <i>Pharmaceutical Research</i> , Vol. 6, May 1999, pp. 408-412.	
	C7	Montel et al., "Development of a New Tablet Formulation of Theophylline: In Vitro and In Vivo Studies," <i>Drug Development and Industrial Pharmacy</i> , Vol. 9, No. 3, 1983, pp. 399-420.	
SH	C8	Arias et al., "Dissolution Properties and In Vivo Behaviour of Triamterene in Solid Dispersions With Polyethylene Glycols," <i>Pharm-Acta-Helv</i> , Vol. 71, No. 4, 1996, pp. 229-235.	

Examiner  
Signature

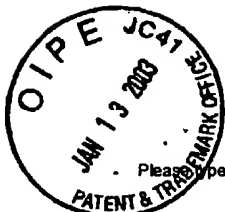
Date  
Considered

6/11/04

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.



Please type a plus sign (+) inside this box → ☐

PTO/SB/08A (08-00)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)		<b>Complete if Known</b>	
		Application Number	09/654,227
		Filing Date	August 31, 2000
		First Named Inventor	Wolfgang HEIL et al.
		Group Art Unit	1617
		Examiner Name	M. Bahar
Sheet 2 of 2	Attorney Docket Number	PLOVIN-1A	

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
SH	C9	Berlin et al., "Phase I and Pharmacokinetic Study of a Micronized Formulation of Carboxyamidotriazole, A Calcium Signal Transduction Inhibitor: Toxicity, Bioavailability And The Effect Of Food," <i>Clinical Cancer Research</i> , January 2002, Vol. 8, No. 1, pp. 86-94	
	C10	Carlson et al., "Efficacy And Safety Of Reformulated, Micronized Glyburide Tablets In Patients With Non-Insulin-Dependent Diabetes Mellitus: A Multicenter, Double-Blind, Randomized Trial," <i>Clinical Therapeutics</i> , 1993, Vol. 15, No. 5, pp. 788-96.	
	C11	Duclos et al., "About A Pharmacokinetic Study Of Progesterone In Cemeils," <i>Eur-J-Drug-Metab-Pharmacokin</i> , Vol. 15, No. 2, Suppl., Abstr. 226, 1990.	
	C12	Fell et al., "Bioavailability Of Griseofulvin From A Novel Capsule Formulation," <i>The Journal Of Pharmacy And Pharmacology</i> , 1978, Vol. 30, No. 8, pp. 479-82.	
	C13	Hartmann et al., "Comparison Of Galenic Formulations Of Orlistate (Tetrahydrolipstatin). A Pharmacological Approach," <i>Drug Investigation</i> , 1993, Vol/Iss/Pg. 5/1 (44-50).	
	C14	Kohn et al., "Pharmacokinetics And Bioavailability Of Diltiazem (CRD-401) In Dog," <i>Arzneimittel-Forschung</i> , 1977, Vol. 27, No. 7, pp. 1424-8.	
	C15	Hsiao et al., "Method For Preparing An Oral Formulation Containing Acid-Sensitive Drugs," <i>Standard Chem. &amp; Pharm. Co., Ltd.</i>	
	C16	Klokkers et al., "Stabilization Of Acid Sensitive Benzimidazoles With Amino Acid/Cyclodextrin Combinations."	
	C17	Bruzzese et al., "Action Of Gastric And Intestinal Simulated Juice On Mepartricin Stability In Solid And Solubilized Form," <i>Il Farmaco-Ed. Pr.</i> , Vol. 32, No. 8, pp. 422-428.	
	C18	Anderson et al., "Pharmacokinetics And Bioavailability Of Omeprazole After Single And Repeated Oral Administration In Healthy Subjects," <i>Br. J. Clin. Pharmac.</i> , 1990, Vol. 29, pp. 557-563.	
SH	C19	Bozdag et al., "Formulation And Stability Evaluation Of Enteric-Coated Omeprazole Formulations," <i>S.T.P. Pharma Sciences</i> , Vol. 9, No. 4, 1999, pp. 321-327.	

Examiner Signature		Date Considered	6/11/04
--------------------	--	-----------------	---------

\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.



RECEIVED

JUL 15 2003

Please type a plus sign (+) inside this box →

Approved for use through 10/31/2003

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)		<b>Complete if Known</b>			
		Application Number	09/654,227		
		Filing Date	August 31, 2000		
		First Named Inventor	Wolfgang HEIL et al.		
		Group Art Unit	1617		
		Examiner Name	M. Bahar		
Sheet	1	of	1	Attorney Docket Number	PLOVIN-1A

U.S. PATENT DOCUMENTS					
Examiner Initials *	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
		Number	Kind Code <sup>2</sup> (if known)		
SH	A1	5,827,843		Koninckx	10-27-1998

FOREIGN PATENT DOCUMENTS								
Examiner Initials *	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>3</sup>
		Office <sup>4</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
SH	B1	WO	98/27929	A2	Nashed	07-02-1998		Yes

NON PATENT LITERATURE DOCUMENTS					
Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.			T <sup>2</sup>

Examiner Signature		Date Considered	6/11/04
-----------------------	--	--------------------	---------

<sup>1</sup> EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>2</sup> Unique citation designation number. <sup>3</sup> See attached Kinds of U.S. Patent Documents. <sup>4</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>5</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>6</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>7</sup> Applicant is to place a check mark here if English language Translation is attached.

Please type a plus sign (+) inside this box → +

PTO/SB/08A (08-00)

Approved for use through 10/31/2002. OMB 0851-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 of 1

### Complete if Known

Application Number	09/654,227
Filing Date	August 31, 2000
First Named Inventor	Wolfgang HEIL et al.
Group Art Unit	1617
Examiner Name	M. Bahar
Attorney Docket Number	PLOVIN-1A

### U.S. PATENT DOCUMENTS

Examiner Initials *	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
		Number	Kind Code <sup>2</sup> (if known)		

**RECEIVED**

DEC 12 2003

TECH CENTER 1600/2900

### FOREIGN PATENT DOCUMENTS

Examiner Initials *	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>3</sup>
		Office <sup>2</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				

### NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
SH	C1	Ellman Declaration with Exhibits A-M	

Examiner  
Signature

*[Handwritten Signature]*

Date  
Considered

6/11/04

\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

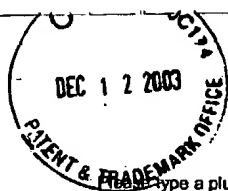
<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

### CERTIFICATION OF MAILING

I hereby certify that this correspondence is being deposited with the U.S. Postal Services as First Class Mail in an envelope addressed to: Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on: December 4, 2003

Name: Sharon McDaniel

Signature: *[Handwritten Signature]*  
Millen, White, Zelano & Branigan, P.C.



Type a plus sign (+) inside this box → ☐

PTO/SB/08A (08-00)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet

1

of

4

### Complete if Known

Application Number	09/654,227
Filing Date	August 31, 2000
First Named Inventor	Wolfgang HEIL et al.
Group Art Unit	1617
Examiner Name	M. Bahar
Attorney Docket Number	PLOVIN-1A

### U.S. PATENT DOCUMENTS

Examiner Initials *	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
		Number	Kind Code <sup>2</sup> (if known)		
SH	A1	4,217,347		Horovitz et al.	08-12-1980
	A2	5,001,113		Williams et al.	03-19-1991
	A3	5,824,667		Spona et al.	10-20-1998
	A4	6,083,528		Elliesen et al.	07-04-2000
	A5	6,121,465		Mohr et al.	09-19-2000
	A6	RE37,564		Spona et al.	02-26-2002

### FOREIGN PATENT DOCUMENTS

Examiner Initials *	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>2</sup>
		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
SH	B1	DE	3022337	A1	Elger et al.	01-07-1982		
	B2	WO	95/07081	A1	Koninckx	03-16-1995		
	B3	WO	97/10827	A1	Petit et al.	03-27-1997		
	B4	WO	98/27929	A2	Nashed	07-02-1998		

### NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
SH	C1	Elstein et al., "Advances in Oral Hormonal Contraception," <i>Zentralbl Gynakol</i> 117 (1995) 559-565	
	C2	Oelkers et al., "Effects of the new progestogen and antimineralocorticoid dihydrospirorenone," <i>Acta Endocrinologica</i> 1992: 126 Suppl. 4, p. 71	
	C3	Oelkers et al., (1991) "Dihydrospirorenone, a New Progestogen with Antimineralocorticoid Activity: Effects on Ovulation, Electrolyte Excretion, and the Renin-Aldosterone System in Normal Women" <i>Journal of Clinical Endocrinology and Metabolism</i> , Vol. 73, No. 4, 837-842	
	C4	Oelkers, "Effects of oral contraceptives on the renin - aldosterone system: overview and report on a new natriuretic progestogen," <i>Advances in Contraception</i> , 7 Suppl. 3 (1991) 195-206	
SH	C5	Kinci et al., "Increasing Oral Bioavailability of Progesterone by Formulation," <i>Journal of Steroid Biochemistry</i> , 1978, Vol. 9, pp. 83-84	

Examiner  
Signature

Date  
Considered

6/11/04

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.



Please type a plus sign (+) inside this box →



PTO/SB/089 (08-00)  
Approved for use through 10/31/2002. OMB 0851-0061  
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE  
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet

2

of

4

Complete if Known

Application Number	09/654,227
Filing Date	August 31, 2000
First Named Inventor	Wolfgang HEIL et al.
Group Art Unit	1617
Examiner Name	M. Bahar
Attorney Docket Number	PLOVIN-1A

### NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
SM	C6	Whitehead et al., "Absorption and metabolism of oral progesterone," <i>British Medical Journal</i> , 22 March 1980, pp. 825-827	
	C7	Maxson et al., "Bioavailability of oral micronized progesterone," <i>Fertility and Sterility</i> , Vol. 44, No. 5, November 1985, pp. 622-626	
	C8	Chakmakjian et al., "Bioavailability of Progesterone with Different Modes of Administration," <i>The Journal of Reproductive Medicine</i> , Vol. 32, No. 6, June 1987, pp. 443-448	
	C9	Hargrove et al., "Absorption of oral progesterone is influenced by vehicle and particle size," <i>Am J Obstet Gynecol</i> , Vol. 161, No. 4, October 1989, pp. 948-951	
	C10	Kohno et al., "Pharmacokinetics and Bioavailability of Diltiazem (CRD-401) in Dog," <i>Arzneim.-forsch./Drug Res.</i> , 27 (II), No. 7 (1977), pp. 1424-1428	
	C11	Nürnberg, "Manufacturing and Properties of Pharmaceutical Spray-Dried Products," <i>Acta Pharmaceutica Hungarica</i> 48. 19-35. 1978 (and English translation)	
	C12	Lehto et al., "The Effect of pH on the In-vitro Dissolution of Three Second-generation Sulphonylurea Preparations: Mechanism of Antacid-sulphonylurea Interaction," <i>J. Pharm. Pharmacol.</i> 1996, 48: 899-901	
	C13	Clarke et al., "Factors Influencing Comparative Bioavailability of Spironolactone Tablets," <i>Journal of Pharmaceutical Sciences</i> , Vol. 66, No. 10, October 1977, pp. 1429-1432	
	C14	"Bioavailability and Bioequivalence," <i>Biopharmacy</i> , Chapter 7 (English translation part 1/2 of page 202, Chapter 7)	
	C15	Berger et al., (1992) "Influence of Different Progestogens on Blood Pressure of Non-Anaesthetized Male Spontaneously Hypertensive Rats" <i>Contraception</i> 46: 83-97	
	C16	Skouby, (2000) "The rationale for a wider range of progestogens" <i>Climacteric</i> , Vol. 3, (Suppl. 2): 14-20	
	C17	Norman et al., (2000) "Drospirenone" <i>Drugs of the Future</i> 2000, 25(12): 1247-1256	
	C18	R. Krattenmacher, (2000) "Drospirenone: pharmacology and pharmacokinetics of a unique progestogen" <i>Contraception</i> 62, 29-38	
	C19	Fuhrmann et al., (1996) "The Novel Progestin Drospirenone and its Natural Counterpart Progesterone: Biochemical Profile and Antiandrogenic Potential" <i>Contraception</i> , 54: 243-251	
SH	C20	Parsey et al., (2000) "An Open-Label, Multicenter Study to Evaluate Yasmin, a Low-Dose Combination Oral Contraceptive Containing Drospirenone, a New Progestogen" <i>Contraception</i> , 61: 105-111	

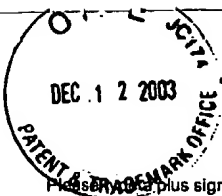
Examiner  
Signature

Date  
Considered

6/11/04

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.



Please place a plus sign (+) inside this box →



PTO/SB/08A (08-00)

Approved for use through 10/31/2002. OMB 0651-0031  
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 3 of 4

**Complete if Known**

Application Number	09/654,227
Filing Date	August 31, 2000
First Named Inventor	Wolfgang HENIG et al.
Group Art Unit	1617
Examiner Name	M. Bahar
Attorney Docket Number	PLOVIN-1A

**RECEIVED**  
DEC 18 2003  
REGISTRATION CENTER 1600/2900**NON PATENT LITERATURE DOCUMENTS**

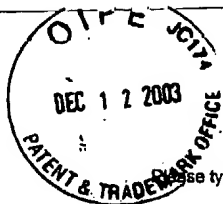
Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
64	C21	Krause et al., "Isolation and Identification of Spirorenone Metabolites from the Monkey ( <i>Macaca Fascicularis</i> )," <i>Steroids</i> , Vol. 40, No. 1, July 1982, pp. 81-90	
	C22	Krause et al., "Determination of Plasma Levels of Spirorenone, a New Aldosterone Antagonist, and One of its Metabolites by High-Performance Liquid Chromatography," <i>Journal of Chromatography</i> , 230 (1982) 37-45	
	C23	"Spirorenone," <i>Drugs of the Future</i> , Vol. 10, No. 6, 1985, pp. 479-481	
	C24	Wilson et al., (1984) "A prospective controlled study of the effect on blood pressure of contraceptive preparations containing different types and dosages of progestogen" <i>Brit. J. Obstet Gynecol</i> 91, 1254-1260	
	C25	Nichols et al., (1993) "Effect of four combined oral contraceptives on blood pressure in the pill-free interval" <i>Contraception</i> 47, 367-376 (1993)	
	C26	Oelkers et al., (1974) "Effects of Progesterone and Four Synthetic Progestagens on Sodium balance and the Renin-Aldosterone System in Man" <i>J. Clin. Endocrinol Metab</i> 39, 882-890	
	C27	Ryland et al., "Natural progesterone and antihypertensive action," <i>British Medical Journal</i> , Vol. 290, Jan. 5, 1985, p. 13-14	
	C28	Luotola, "Blood Pressure and Hemodynamics in Postmenopausal Women During Estradiol-17 $\beta$ Substitution," <i>Annals of Clinical Research</i> , Vol. 15, Suppl. 38 1983	
	C29	Mashchak, et al., "Estrogen Replacement Therapy and Hypertension," <i>The Journal of Reproductive Medicine</i> , Vol. 30, No. 10 (Supp)/October 1985, p. 805-810	
	C30	Rajkumar et al., "Hormonal Therapy Increases Arterial Compliance in Postmenopausal Women," <i>JACC</i> , Vol. 30, No. 2, August 1997:350-6	
	C31	Hayward et al., "Effect of hormone replacement therapy on non-invasive cardiovascular haemodynamics," <i>Journal of Hypertension</i> , 1997, Vol. 15, No. 9, p.987-993	
	C32	Mercuro et al., "Estradiol-17 $\beta$ Reduces Blood Pressure and Restores the Normal Amplitude of the Circadian Blood Pressure Rhythm in Postmenopausal Hypertension," <i>American Journal of Hypertension</i> , Vol. 11, No. 8, Part 1, pp. 909-913	
	C33	Hayward et al., "Effect of Combination Hormone Replacement Therapy on Ambulatory Blood Pressure and Arterial Stiffness in Diabetic Postmenopausal Women," <i>American Journal of Hypertension</i> , July 2001, Vol. 14, No. 7, Part 1, pp. 699-703	
	C34	Wren et al., "The effect of type and dose of oestrogen on the blood pressure of post-menopausal women," <i>Maturitas</i> , 5 (1983) 135-142	
64	C35	Oelkers, "Reply to Letter to the Editor," <i>Gynecol Endocrinol</i> , 2000, 14:476-478	

Examiner  
SignatureDate  
Considered

6/11/04

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.



Please type a plus sign (+) inside this box → ☐

PTO/SB/08A (08-00)

Approved for use through 10/31/2002. OMB 0851-0031  
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO		<b>Complete if Known</b>			
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)		Application Number	09/654,227		
		Filing Date	August 31, 2000		
		First Named Inventor	Wolfgang HEIL et al.		
		Group Art Unit	1617		
		Examiner Name	M. Bahar		
Sheet	4	of	4	Attorney Docket Number	PLOVIN-1A

RECEIVED  
DEC 18 2003  
TECH CENTER 1600/2000

NON PATENT LITERATURE DOCUMENTS		
Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
SH	C36	Seely et al., "Estradiol With or Without Progesterone and Ambulatory Blood Pressure in Postmenopausal Women," <i>The American Heart Association, Inc.</i> , May 1999, 1190-1194
	C37	Mercuro et al., "Effects of Acute Administration of Transdermal Estrogen on Postmenopausal Women with Systemic Hypertension," <i>The American Journal of Cardiology</i> , Vol. 80, September 1, 1997, 652-655
	C38	"Effects of Estrogen or Estrogen/Progestin Regimens on Heart Disease Risk Factors in Postmenopausal Women," <i>JAMA</i> , January 18, 1995, Vol. 273, No. 3, 199-208
	C39	Pripp et al., "A randomized trial o effects of hormone replacement therapy on ambulatory blood pressure and lipoprotein levels in women with coronary artery disease," <i>Journal of Hypertension</i> , 1999, Vol. 17, No. 10, 1379-1386
	C40	Manhem et al., "Transdermal oestrogen reduces daytime blood pressure in hypertensive women," <i>Journal of Human Hypertension</i> , (1998) 12, 323-327
	C41	Ittersum et al., "Ambulatory-Not Office-Blood Pressures Decline During Hormone Replacement Therapy in Healthy Postmenopausal Women," <i>American Journal of Hypertension</i> , 1998, Vol. 11, No. 10, part 1, 1147-1152
	C42	Carara et al., "Abstracts Thirtieth Annual Meeting American College of Clinical Pharmacology September 23-25, 2001, Vienna, Virginia," <i>J Clin Pharmacol</i> , 2001; 41:1014-1033
	C43	Epstein, "Aldosterone and the hypertensive kidney: its emerging role as a mediator of progressive renal dysfunction: a paradigm shift," <i>Journal of Hypertension</i> , 2001, Vol. 19, No. 5, 829-834
	C44	Duprez et al., "Aldosterone and Vascular Damage," <i>Current Hypertension Reports</i> , 2000, 2:327-334
	C45	Pitt et al., "The Effect of Spironolactone on Morbidity and Mortality in Patients with Severe Heart Failure," <i>The New England Journal of Medicine</i> , Vol. 341, No. 10, September 2, 1999, 709-717
	C46	Farquharson et al., "Spironolactone Increases Nitric Oxide Bioactivity, Improves Endothelial Vasodilator Dysfunction, and Suppresses Vascular Angiotensin I/Angiotensin II Conversion in Patients with Chronic Heart Failure," <i>Circulation</i> , February 15, 2000, 594-597
	C47	MacFadyen et al., "Aldosterone blockade reduces vascular collagen turnover, improves heart rate variability and reduces early morning rise in heart rate in heart failure patients," <i>Cardiovascular Research</i> , 35 (1997) 30-34
SH	C48	Chrysostomou et al., "Spironolactone in Addition to ACE Inhibition to Reduce Proteinuria in Patients with Chronic Renal Disease," <i>N Engl J Med</i> , Vol. 345, No. 12, September 20, 2001, 925-926

Examiner Signature		Date Considered	6/11/04
--------------------	--	-----------------	---------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.



Please type a plus sign (+) inside this box → +

PTO/SB/08A (08-00)

Approved for use through 10/31/2002. OMB 0651-0031  
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(use as many sheets as necessary)</i>				<b>Complete if Known</b>	
Application Number		09/654,227			
Filing Date		August 31, 2000			
First Named Inventor		Wolfgang HEIL et al.			
Group Art Unit		1617			
Examiner Name		M. Bahar			
Attorney Docket Number		PLOVIN-1A			
Sheet	1	of	1		

U.S. PATENT DOCUMENTS					
Examiner Initials *	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
		Number	Kind Code <sup>2</sup> (if known)		
	A1				
	A2				
	A3				
	A4				
	A5				
	A6				
	A7				

FOREIGN PATENT DOCUMENTS								
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
	B1							
	B2							
	B3							
	B4							
	B5							
	B6							
	B7							

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
SM	C1	An invitation (one page) for and 21 slides shown in an oral presentation held on February 17, 1988 in Berlin, Germany, entitled "Studies on pH-dependent Isomerization of Pregnene-17,21-Carbolactones," by Johannes W. Tack. (Original in German with English translation.)	
SM	C2	Sattar, et al., J.Clin.Endocrin.&Metab., Vol. 82, No. 8, 1483-2491 (1997).	
	C3		

Examiner Signature		Date Considered	6/11/04
-----------------------	--	--------------------	---------

\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

**PAYMENT OF FEES DUE (IF ANY):**

- ☒ A check for \$180.00 covering the fee identified above is attached.
- ☐ Please charge to Deposit Account No. 13-3402 \$\_\_\_\_\_ for the fee identified above.
- ☒ The Commissioner is hereby authorized to charge or credit any overpayment to Deposit Account No. 13-3402, two copies of this paper are attached for that purpose.

Respectfully submitted,

Anthony J. Zelano, Reg. No. 27,709  
John A. Sopp, Reg. No. 33,103  
Attorneys for Applicants

MILLEN, WHITE, ZELANO &  
BRANIGAN, P.C.  
Arlington Courthouse Plaza 1, Suite 1400  
2200 Clarendon Boulevard  
Arlington, Virginia 22201  
Telephone: (703) 243-6333  
Facsimile: (703) 243-6410

Attorney Docket No.: PLOVIN-1ADate: February 26, 2004

USPTO Form PTO/US 101 (Rev. 10-1-99)

- 4 -

*Copy*

Please type a plus sign (+) inside this box ☐

Approved for use through 10/31/02. PTO/US 101 (Rev. 10-1-99)

U.S. Patent and Trademark Office, U.S. DEPARTMENT OF COMMERCE

Substitute for form 100-P/PTO

**INFORMATION DISCLOSURE STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 1 of 1

Application Number: 09/654,237

Filing Date: August 31, 2000

First Named Inventor: Wolfgang H. H. H. H.

Group A Inventor: 1517

Applicant Name: M. Bahr

Attorney Docket Number: PLOVIN-1A

Examiner Index	Case No.	U.S. Patent Document Number	Kind Code (if known)	Name of Patentee or Applicant of U.S. Patent Document	Date of Publication of U.S. Patent Document (MM-DD-YYYY)
A1					
A2					
A3					
A4					
A5					
A6					
A7					

Examiner Index	Case No.	Foreign Patent Document Number	Kind Code (if known)	Name of Patentee or Applicant of Foreign Document	Date of Publication of Foreign Document (MM-DD-YYYY)	Page 1, Summary, Claim or Abstract (if known)	Page 2, Summary, Claim or Abstract (if known)
B1							
B2							
B3							
B4							
B5							
B6							
B7							

Examiner Index	Case No.	Non Patent Literature Document	Date of Publication of Non Patent Literature Document (MM-DD-YYYY)	Page 1, Summary, Claim or Abstract (if known)	Page 2, Summary, Claim or Abstract (if known)
C1					
C2					
C3					

Examiner Signature: \_\_\_\_\_ Date Considered: \_\_\_\_\_

\*EXAMINER INDEX: A reference considered, whether or not citation is in conformity with MPEP 609. Draw line through citation if not in conformity and not considered. Include copy of the form with next communication to applicant.

\*Unique citation designation number: \* See attached kinds of U.S. Patent Documents. \* Enter Office that issued the document. \* The two-letter code (WFO Standard ST 3). \* For Japanese patent documents, the location of the year of the region of the patent must be made the same as the year of the patent document. \* Kind of document by the appropriate symbol is indicated on the document under WFO Standard ST 3. \* To it.